



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1010]

Completeness Assessments for Type II Active Pharmaceutical Ingredient Drug Master Files

Under the Generic Drug User Fee Amendments of 2012; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled "Completeness Assessments for Type II API DMFs Under GDUFA". It finalizes the draft guidance entitled "Initial Completeness Assessments for Type II API DMFs Under GDUFA", which published on October 2, 2012. This guidance is intended for holders of Type II active pharmaceutical ingredient (API) drug master files (DMFs) that are or will be referenced in an abbreviated new drug application (ANDA), an amendment to an ANDA, a prior approval supplement (PAS) to an ANDA, or an amendment to a PAS (generic drug submissions).

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-D-1010 for "Completeness Assessments for Type II API DMFs Under GDUFA". Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions,"

publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 1669, Silver Spring, MD 20993-0002, 240-402-7930; or Huyi Zhang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 75, rm. 6604, Silver Spring, MD 20993-0002, 240-402-8843; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Completeness Assessments for Type II API DMFs Under GDUFA". This guidance is intended for holders of Type II API DMFs that are or will be referenced in an ANDA, an amendment to an ANDA, a PAS to an ANDA, or an amendment to a PAS (generic drug submissions). The guidance makes

recommendations about the information that should be included in the DMF to facilitate a Generic Drug User Fee Amendments of 2012 (GDUFA) Completeness Assessment (CA). The guidance does not apply to Type II API DMFs used to support new drug applications (NDAs), biologics license applications, other submissions that are not generic drug submissions, or any other types of DMFs.

Under GDUFA, beginning October 1, 2012, the holder of a Type II API DMF must pay a one-time DMF fee when the DMF is first referenced in a generic drug submission submitted to FDA on the basis of a letter of authorization from the DMF holder. Also under GDUFA, holders of Type II API DMFs that were evaluated before October 1, 2012, must pay a one-time fee for the DMF when their DMF is first referenced in a new ANDA, an ANDA amendment, or an ANDA PAS on or after October 1, 2012. Only Type II API DMFs for use in generic drug submissions incur this one-time fee. Type II API DMFs intended for reference in a generic drug submission for which the fee is paid will undergo a CA. Although the requirement for a CA for Type II API DMFs is new, FDA has previously evaluated DMFs in accordance with the criteria set out in the GDUFA Completeness Assessment Checklist for Type II API DMFs (CA Checklist), attached to the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Completeness Assessments for Type II API DMFs Under GDUFA". It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.regulations.gov>.

Dated: February 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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